

IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

SUPERNUS PHARMACEUTICALS, INC;
and UNITED THERAPEUTICS
CORPORATION,

Plaintiffs,

v.

MICHELLE K. LEE, Under Secretary of
Commerce for Intellectual Property and
Director of the United States Patent and
Trademark Office

Defendant.

Case No. 1:16-cv-00342-GBL-IDD

MEMORANDUM OPINION AND ORDER

THIS MATTER is before the Court on the parties' cross-motions for summary judgment. Dkts. 15, 16 ("Pltf. Motion"); Dkts. 18, 19 ("Def. Motion"). This is an Administrative Procedure Act ("APA") appeal of the United States Patent and Trademark Office's ("PTO") determination of patent term adjustment ("PTA") for Plaintiffs Supernus Pharmaceuticals, Inc. and United Therapeutic Corporation's patent, U.S. Patent No. 8,747,897 ("the '897 patent"). The issue before the Court is whether the determination of patent term adjustment was contrary to law or arbitrary and capricious under the APA.

The Court **GRANTS** Defendant's Motion for Summary Judgment and **DENIES** Plaintiffs' Motion for Summary Judgment for three reasons. First, the Court holds that the USPTO's decision was not in violation of the Administrative Procedure Act because the Federal Circuit's decision in *Gilead Sciences, Inc. v. Lee*, 778 F.3d 1341 (Fed. Cir. 2015) forecloses Plaintiffs' claim that 37 C.F.R. §1.704(c)(8) is arbitrary, capricious, or otherwise not in

accordance with law. Second, the Court finds that 37 C.F.R. § 1.704(d)(1) is similarly not arbitrary, capricious, or otherwise not in accordance with law because Plaintiffs have not adequately demonstrated that § 1.704(d)(1) reflects an inappropriate interpretation of the PTA statute. Additionally, Plaintiffs failed to assert the argument that § 1.704(d)(1) is arbitrary, capricious, or otherwise not in accordance with law during administrative review. Third, Plaintiffs have failed to demonstrate that a government taking in violation of the Fifth Amendment occurred.

BACKGROUND

Plaintiffs are Supernus Pharmaceuticals, Inc. (“Supernus”) and United Therapeutics Corporation (“UTC”) (together “Plaintiffs”). Dkt.1, (“Compl.”) ¶¶ 4,5. Supernus is a specialty pharmaceutical company focused on developing and commercializing products for the treatment of central nervous system disorders. *Id.* ¶ 4. Supernus is the owner and assignee of United States Patent No. 8,747,897 (“the ‘897 patent”), titled “OSMOTIC DRUG DELIVERY SYSTEM,” which is the patent at issue. *Id.* ¶ 1. UTC is a biotechnology company focused on the development and commercialization of products designed to address the needs of patients with chronic and life-threatening conditions. *Id.* ¶ 5. UTC is the exclusive licensee of the ‘897 patent. *Id.* ¶ 1. For some of the period during prosecution, UTC took over the right to prosecute the patent application and took actions as the applicant in that capacity. Compl. ¶ 12. Accordingly, for the sake of clarity and simplicity, “Applicant” and “Patentee” are used herein to refer to Supernus and/or UTC as appropriate for the given time frame. *Id.*

The facts in this case are not in dispute. On April 27, 2006, Applicant applied for the ‘897 patent by filing application number 11/412,100 (“the ‘100 application”) with the United

States Patent and Trademark Office (PTO).¹ *Id.* ¶ 10. Concurrently, on April 27, 2006, Applicant filed international application number PCT/US2007/09969, which claims priority to the ‘100 application. *Id.* ¶ 4. This international application entered the European Regional phase as European application number 07755989.6. *Id.* ¶ 13.

On August 20, 2010, the PTO mailed a final Rejection addressing the then-pending claims of the ‘100 application. *Id.* ¶ 14. On February 22, 2011, Applicant filed a Request for Continued Examination (“RCE”) along with an Information Disclosure Statement (“IDS”) amendment, and remarks responsive to the Final Rejection mailed on August 20, 2010. *Id.* ¶ 15. On October 13, 2011, the European Patent Office (“EPO”) published its decision to grant European patent number EP2010189 for the EP application. *Id.* ¶ 16. On August 21, 2012, the EPO issued a Communication (“EPO Communication”) containing a Notice of Opposition regarding an opposition filed by Sandoz AG (“the Sandoz Opposition”) on August 8, 2012, against the grant of the EP patent. *Id.* ¶ 17. The Sandoz Opposition cited ten documents. *Id.* ¶ 18.

On September 11, 2012, Applicant received a letter from its European Patent attorney disclosing the Sandoz Opposition filed against the grant of the EP patent. *Id.* ¶ 19. On November 29, 2012, Applicant submitted an IDS to the PTO, informing the PTO of the Sandoz Opposition. *Id.* ¶ 20. Applicant also submitted the documents cited in the Sandoz Opposition, the Sandoz Opposition itself, the EPO Communication dated August 21, 2012, and the letter from Applicant’s European Patent attorney. *Id.* ¶ 21. On September 13, 2013, the PTO issued the first Office action after the February 22, 2011 filing of the RCE. *Id.* ¶ 21. On January 10, 2014, Applicant filed a response to the first Office action after the filing of the RCE. *Id.* ¶ 22. On February 4, 2014, the PTO issued a Notice of Allowance. *Id.*

On June 10, 2014, the PTO published the ‘897 patent, reflecting a patent term adjustment (“PTA”) of 1,260 days on the face of the patent. *Id.* ¶ 24. On August 5, 2014, Patentee filed a request for Reconsideration of Patent Term Adjustment to revise the PTA to 2,030 days. *Id.* ¶ 26. The Patentee argued that the PTA reduction of 646 days, that is, the 646 day interval between the (a) February 22, 2011 filing of the RCE and (b) the November 29, 2012 filing of the IDS triggered by the EPO Communication, was improperly characterized as applicant delay. *Id.* Patentee also argued that the ‘897 patent was entitled to an additional 126 days of PTA under 35 U.S.C. § 154(b)(1)(B). *Id.*

On July 2, 2015, the PTO mailed a Redetermination of Patent Term Adjustment, awarding patentee an additional 126 days of PTA under 35 U.S.C. § 154(b)(1)(B). *Id.* ¶ 27. However, the PTO rejected the request to eliminate the 646 day deduction of Applicant delay in light of the Federal Circuit’s decision in *Gilead Sciences, Inc. v. Lee*, 778 F.3d 1341 (Fed. Cir. 2015). Dkt. 13 (“Administrative Record”) at A441. On July 9, 2015, Patentee filed a second Request for Reconsideration of Patent Term Adjustment to request the PTO to revise the PTA of 1,386 days to 2,032 days. Compl. ¶ 28. Patentee argued that the deduction of 646 days from the PTA as Applicant delay under 37 C.F.R. 1.704(c)(8) was improper and that the Applicant delay was zero days. *Id.* On September 30, 2015, the PTO issued a second Decision on Patent Term Adjustment, denying the patentee’s request to the PTA reduction of 646 days as applicant delay and affirming the PTA of 1,386 days. *Id.* ¶ 29.

On March 28, 2016, Plaintiffs filed a complaint against Michelle K. Lee, the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office. Dkt. 1. On June 17, 2016, Plaintiffs filed a Motion for Summary Judgment to correct the Patent Term Adjustment of the ‘897 Patent. Dkts. 15, 16. On July 8, 2016,

Defendant Lee filed a brief that contained both her Cross Motion for Summary Judgment and her opposition to Plaintiff's Motion for Summary Judgment. Dkts. 18, 19, 20. Both motions are currently before the Court.

DISCUSSION

A. Standard of Review

I. Statutory Framework

The term of a patent is governed by 35 U.S.C. § 154. Under § 154, a patent grant is issued for twenty years measured from the earliest filing date of the application. 35 U.S.C. § 154. Congress created a provision under which a patent owner can seek a patent term adjustment ("PTA") for certain delays caused by the PTO between the filing and issuance of a patent. Section 154(b)(1) outlines the general sources of delay for which a PTA can be sought. The first, commonly referred to as "A Delay," allows for a patent term extension if the PTO fails to provide a notification under 35 U.S.C. § 132 or a notice of allowance within fourteen months of an application filing. 35 U.S.C. § 154(b)(1)(A)(i). The second, commonly referred to as "B Delay," allows for a one day extension for every day that the PTO fails to issue a patent after three years have passed between the application and allowance dates. *Id.* at § 154(b)(1)(B). Lastly, "C Delay" allows a PTA for some types of delays excluded from the computation of a "B Delay." *Id.* at § 154 (b)(1)(C).

An applicant's conduct also impacts the calculation of a PTA. Specifically, PTA is reduced by a period of time equal to the number of days which an applicant "failed to engage in reasonable efforts to conclude prosecution of the application." *Id.* at § 154(b)(2)(C)(iii). "Congress expressly delegated authority to the PTO by granting authority to '[t]he Director [to] prescribe regulations establishing the circumstances that constitute a failure of an applicant to

engage in reasonable efforts to conclude processing or examination of an application.” *Gilead*, 778 F.3d at 1349 (quoting 35 U.S.C. § 154(b)(2)(C)(iii)). Pursuant to its rulemaking authority, the PTO promulgated 37 C.F.R. § 1.704, which delineates various circumstances that *per se* “constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application.” 37 C.F.R. § 1.704(c). Of particular importance to this case is 37 C.F.R. § 1.704(c)(8), which reads as follows:

Circumstances that constitute a failure of the applicant to engage in reasonable efforts to conclude processing or examination of an application . . . include the following circumstances[:] . . . Submission of a supplemental reply or other paper; other than a supplemental reply or other paper expressly requested by the examiner, after a reply has been filed, in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the day after the date the initial reply was filed and ending on the date that the supplemental reply or other such paper was filed.

37 C.F.R. § 1.704(c)(8).

The PTO also established a “safe harbor” provision for applicants who promptly file an IDS within 30 days of receiving new material from either (1) a foreign patent office; or, (2) the PTO itself. 37 C.F.R. § 1.704(d)(1). Both 37 C.F.R. § 1.704(c)(8) and § 1.704(d)(1) are at issue in this case.

II. Unambiguous Statutory Language

“As always, the ‘starting point in every case involving construction of a statute is the language itself.’” *United States v. Hohri*, 482 U.S. 64, 68 (1987) (quoting *Kelly v. Robinson*, 479 U.S. 36, 43 (1986)). “If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.” *City of Arlington v. FCC*, 133 S. Ct. 1863, 1868 (2013). To the extent that an agency’s interpretation is at odds with the plain language of an unambiguous statute, no deference is afforded to that interpretation. *Smith v. City of Jackson, Miss.*, 544 U.S. 228, 267 (2005).

III. Ambiguous Statutory Language

When a court reviews a challenge to an agency's construction of a statute administered by that agency, it will follow the two-step approach set out in *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842 (1984). First, the *Chevron* approach asks whether Congress has spoken on the precise issue. *City of Arlington*, 133 S. Ct. at 1868. Second, if Congress has not addressed the question and explicitly left a gap for the agency to fill, the Court asks whether the agency's construction and application of the statute is permissible. *Id.* The Supreme Court has held that the agency's view will govern "if it is a reasonable interpretation of the statute—not necessarily the only possible interpretation, nor even the interpretation deemed *most reasonable by the courts.*" *Entergy Corp. v. Riverkeeper, Inc.*, 556 U.S. 208, 218 (2009) (emphasis added).

IV. Summary Judgment

Summary judgment is appropriate where there are no genuine issues of material fact and the reviewing court finds that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a); *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986). The USPTO's patent term adjustment decisions are reviewed under the Administrative Procedure Act ("APA"). See 35 U.S.C. § 154 (b)(4)(A). Under the APA, this Court can only set aside the USPTO's action if it was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706 (2)(A); *Star Fruits S.N.C. v. United States*, 393 F.3d 1277, 1281 (Fed. Cir. 2005). The Court's review is therefore limited to the task of reviewing agency action to determine whether the agency conformed with controlling statutes, and whether the agency has committed a clear error of judgment. *Holly Hill Farm v. United States*, 447 F.3d 258, 263 (4th Cir. 2006).

B. Analysis

The Court grants Defendant's Motion for Summary Judgment and denies Plaintiffs' Motion for Summary Judgment for three reasons. First, the Court holds that the Federal Circuit's decision in *Gilead Sciences, Inc. v. Lee*, 778 F.3d 1341 (Fed. Cir. 2015) forecloses Plaintiffs' claim that 37 C.F.R. § 1.704(c)(8) is arbitrary, capricious, or otherwise not in accordance with law. Second, the Court finds that 37 C.F.R. § 1.704(d)(1) is similarly not arbitrary, capricious, or otherwise not in accordance with law because Plaintiffs have not demonstrated that § 1.704(d)(1) reflects an inappropriate interpretation of the PTA statute. Additionally, Plaintiffs failed to assert the argument that § 1.704(d)(1) is arbitrary, capricious, or otherwise not in accordance with the law during administrative review. Third, Plaintiffs have failed to demonstrate that a government taking has occurred.

a. *Gilead Forecloses Plaintiffs' Claim that 37 C.F.R. § 1.704(c)(8) is Arbitrary, Capricious, or Otherwise Not in Accordance With Law*

The Court grants Defendant's Motion for Summary Judgment because Plaintiffs' claim that 37 C.F.R. § 1.704(c)(8) is arbitrary, capricious, or otherwise not in accordance with law is foreclosed by the Federal Circuit's decision in *Gilead*. The Plaintiff in *Gilead* argued that regulation 37 C.F.R. § 1.704(c)(8), which was created by the PTO in accordance with its rulemaking authority as granted to it by 35 U.S.C. § 154(b)(2)(C)(iii), is arbitrary, capricious, or otherwise not in accordance with the law and in excess of statutory jurisdiction, authority, or limitation. *Gilead*, 778 F.3d at 1346. 37 C.F.R. § 1.704(c)(8) reads as follows:

Circumstances that constitute a failure of the applicant to engage in reasonable efforts to conclude processing or examination of an application . . . include the following circumstances[:] . . . Submission of a supplemental reply or other paper; other than a supplemental reply or other paper expressly requested by the examiner, after a reply has

been filed, in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the day after the date the initial reply was filed and ending on the date that the supplemental reply or other such paper was filed.

(emphasis added).

In affirming the district court's grant of summary judgment in favor of the PTO, the Federal Circuit concluded, after applying the deference standard delineated in *Chevron*, that a "reasonable interpretation of the [PTA] statute is that Congress intended to sanction not only applicant conduct or behavior that results in delay, but also those having the potential to result in delay irrespective of whether such delay actually occurred. *Gilead*, 778 F.3d at 1349. Additionally, the Federal Circuit, quoting the district court, noted that "a supplemental IDS, such as the one that Gilead submitted, [may] force[] an examiner to *go back* and review the application again, while still trying to meet his or her timeliness obligations under § 154." *Id.* at 1350 (quoting *Gilead Sciences, Inc. v. Rea*, 976 F. Supp. 2d 833, 837) (emphasis in original). Moreover, the Court in *Gilead* found that "Congress intended to sanction not only applicant conduct or behavior that result in actual delay, but also those having the potential to result in delay irrespective of whether such delay actually occurred." *Id.* at 1349.

The facts from *Gilead* are similar to the facts presented in this case. In *Gilead*, during patent examination, the patent examiner issued a restriction requirement. *Id.* at 1345. A restriction requirement "informs the applicant that 'two or more independent and distinct inventions are claimed in one application,' and that the applicant is required to elect one of the inventions if the applicant wishes to continue prosecuting the application." *Pfizer, Inc. v. Lee*, 811 F.3d 466, 469 (Fed. Cir. 2016) (quoting 35 U.S.C. § 121). Gilead responded by selecting one group of claims for further examination. *Gilead*, 778 F.3d at 1345. While waiting for the PTO to issue a first office action on the merits, Gilead filed a supplemental IDS 57 days after its

initial response to the restriction requirement. *Id.* The supplemental IDS disclosed two other co-pending patent applications. *Id.* Although the PTO eventually issued the underlying patent, the PTO, in calculating the appropriate PTA, reduced PTA by 57 days as applicant delay. *Id.* This reduction in PTA was challenged by Gilead. *Id.*

Here, Plaintiffs filed an IDS after filing an RCE. Compl. ¶¶ 15, 21. Just as Gilead argued that PTO regulation 37 C.F.R. § 1.704(c)(8) is unreasonable, arbitrary, capricious, and in conflict with the language and intent of 35 U.S.C. § 154 (b)(2)(C)(i) under *Chevron*, Plaintiffs here make the same argument. Dkt. 23 (“Plaintiff Reply”) at 17. The fact that Plaintiffs filed an IDS to comply with their duty of candor owed to the PTO does not change the notion that the IDS filed was a supplemental paper filed in the absence of a request from the PTO. Such a filing forces a patent examiner “to *go back* and review the application again, while still trying to meet his or her timeliness obligations under § 154.” *Gilead*, 778 F.3d at 1350 (quoting *Gilead Sciences, Inc. v. Rea*, 976 F. Supp. 2d 833, 837) (emphasis in original). Moreover, when § 1.704(c)(8) is viewed in conjunction with the thirty day safe harbor provision of 37 C.F.R. § 1.704(d)(1), the Court finds nothing arbitrary, capricious, or unreasonable about reducing PTA in light of an IDS that contains information from a foreign patent office, given that § 1.708(d)(1) allows an applicant to file such an IDS without penalty if filed during the stated 30 day grace period. *See infra* pp. 11-15.

In addition to asserting an argument that § 1.708(c)(8) is valid on its face, Plaintiffs also contend that the PTO erred by applying § 1.704(c)(8) and its full PTA reduction to Plaintiffs’ patent application. Pltf. Motion at 14. Taken these arguments together, Plaintiffs are essentially arguing that they are entitled to an individualized PTA assessment because § 1.704(c)(8) is invalid both facially and as applied to the facts and circumstances of this particular patent

application. As the Supreme Court notes, however, “even if a statutory scheme requires individualized determinations, the decision maker has the authority to rely on rulemaking to resolve certain issues of general applicability unless Congress clearly expresses an intent to withhold that authority.” *Lopez v. Davis*, 531 U.S. 230, 234 (2001) (citation and internal quotation marks omitted). This notion is aligned with the Supreme Court’s rejection of the argument that an agency “must not make categorical exclusions, but may only rely on case-by-case assessments.” *Id.*

Here, the PTA statute does not require the PTO to make any sort of particularized determination of PTA, and instead directs the PTO to promulgate rules of general applicability that address the circumstances that will lead to a deduction of PTA. § 1.708(c)(8) is one of these rules. The Federal Circuit in *Gilead* upheld the reasonableness of the PTO’s interpretation of 35 U.S.C. § 154 by finding that § 1.704(c)(8) is not arbitrary, capricious, or otherwise not in accordance with law. Accordingly, because § 1.704(c)(8) applies squarely to this case, Plaintiffs’ claim must fail as a matter of law. The Court grants Defendant’s Motion for Summary Judgment and denies Plaintiffs’ Motion for Summary Judgment because Plaintiffs’ claim is foreclosed by *Gilead*.

b. Plaintiffs’ Argument That 37 C.F.R. § 1.704(d)(1) is Arbitrary, Capricious, and Otherwise Not In Accordance With Law Similarly Fails

The Court grants Defendant’s Motion for Summary Judgment and denies Plaintiffs’ Motion for Summary Judgment because Plaintiffs have not demonstrated that 37 C.F.R. §1.704(d)(1) is arbitrary, capricious, or otherwise not in accordance with law. The PTO established a “safe harbor” provision for applicants who promptly file an IDS within 30 days of receiving new material from either a foreign patent office or the PTO itself. 37 C.F.R.

§1.704(d)(1). The thirty day period set forth in § 1.704(d)(1) is non-extendable. *See* 37 C.F.R. § 1.704(d)(2). Plaintiffs argue that § 1.704(d)(1), as applied to the facts present in this case, is arbitrary, capricious, and contrary to the PTA statute, inconsistent with the PTO's regulations, and inconsistent with its own practices. Pltf. Motion at 26.

First, Plaintiffs argue that § 1.704(d)(1) is contrary to 35 U.S.C. § 154(b)(2)(C)(i), which provides that PTA should be reduced only if the applicant fails to engage in reasonable efforts to conclude prosecution of the application. *Id.* Plaintiffs contend that in the context of an RCE, § 1.704(d)(1) fails to properly attribute delay caused by the PTO as compared to delay caused by the applicant. *Id.* Plaintiffs assert, *inter alia*, that § 1.704(d)(1) introduces ambiguities by not clearly explicating if the thirty day grace period begins when the foreign attorney receives the communication in question from the European Patent Office, or when the foreign attorney forwards the communication to the applicant. *Id.* at 27

Second, Plaintiffs contend that the thirty day grace period is inconsistent with other PTO regulations. *Id.* To support this argument, Plaintiffs cite 37 C.F.R. § 1.97(b)(4)—which states that an IDS is considered timely filed if it is filed “[b]efore the mailing of a first Office action after the filing of a request for continued examination” under 37 C.F.R. § 1.114. Pltf. Motion at 27. Plaintiffs also cite 37 C.F.R. § 1.97(c), which states that an IDS will be considered by the PTO if filed outside of the time period specified in 37 C.F.R. § 1.97(b) if it is (1) filed before a final Office action or notice of allowance, and (2) accompanied by either a fee or the statement specified in 37 C.F.R. § 1.97(e). Pltf. Motion at 27. 37 C.F.R. § 1.97(e)(1), for example, allots three months for disclosure of new art from foreign prosecution.

Finally, Plaintiffs argue that the non-extendable thirty-day grace period following an RCE is no longer justified under the PTO's new docketing procedures. Pltf. Motion at 28.

Plaintiffs contend that by placing RCEs on the Special New Docket, the PTO is signaling that it is no longer attempting to comply with the time frame imposed by 35 U.S.C. § 154(b)(1)(A)(ii) for RCEs and “is instead emphasizing compact prosecution of original applications.” *Id.* Plaintiffs aggregate these arguments to conclude that the application of § 1.704(d)(1), as applied to the circumstances here is arbitrary and capricious, and contrary to the PTA statute, entitling Plaintiffs to 546 days of PTA. *Id.* at 29.

The Court finds Plaintiffs arguments unavailing. First, Plaintiffs neglected to file their IDS within the 30 day grace period delineated in § 1.704(d)(1), and Plaintiffs failed to do so whether the requisite filing period began when the European attorney received the communication from the European Patent Office, or began when the European attorney forwarded the communication to Plaintiffs. Although Plaintiffs correctly assert that § 1.704(d)(1) does not state when the grace period begins to run, Plaintiffs would have missed the grace period in any event. Plaintiffs European Patent attorney received the European Patent Office communication regarding the Sandoz Opposition on August 22, 2012. *See* Administrative Record at A259. Plaintiffs received a letter from its European Patent attorney informing them of the European Communication on September 11, 2012. Compl. ¶ 19. Accordingly, Plaintiffs should have filed the IDS disclosing the foreign patent office communication by September 21, 2012, or by October 11, 2012.

Instead, Plaintiffs submitted the IDS on November 29, 2012, well outside the window of the 30 day grace period whether the grace period began to run on August 22, 2012, or September 11, 2012. Plaintiffs argument that § 1.704(d)(1) is arbitrary, capricious, or otherwise not in accordance with law because it allegedly creates ambiguities regarding the commencement of the 30 day grace period is without merit in this case, as Plaintiffs have not shown that they would

have met the 30 day deadline in either grace period. If Plaintiffs demonstrated that they met the 30 day grace period in one circumstance but not the other, the argument would be stronger. Plaintiffs, however, cannot save their nonconformance to the rule by arguing *ex post* that § 1.704(d)(1) is arbitrary, capricious, or otherwise not in accordance with law because this case would not be currently before the Court if Plaintiffs filed the IDS in a timely manner. As there was only one, three page document that needed to be translated from a foreign language to English for the IDS, the Court finds that the thirty day grace period presented more than a sufficient amount of time for Plaintiffs to file the IDS in a timely fashion.

To the extent Plaintiffs argue the § 1.704(d)(1) thirty day grace period is inconsistent with other PTO regulations, this argument must also fail. The fact that an IDS may be filed for timely purposes of 37 C.F.R. § 1.97 and still be untimely for § 1.704(c)(8) and § 1.704(d)(1) purposes does not reflect an inconsistency. It simply means that if an applicant would like to maximize its patent term, it would behoove the applicant to file the IDS promptly after receiving communications from a foreign patent office. The PTO is entitled to make this type of a policy decision. Accordingly, the Court finds that implementing a thirty day grace period for filing an IDS after receiving communication from a foreign patent office, as reflected in § 1.704(d)(1), is a reasonable interpretation of 35 U.S.C. § 154(b)(2)(C)(i) and therefore is not arbitrary, capricious, or otherwise not in accordance with law.

Finally, Plaintiffs' argument that the PTO's decision to place RCEs on the new docketing system somehow invalidates § 1.704(d)(1) is also fruitless. Plaintiffs' contention that the non-extendable thirty day grace period following an RCE is no longer justified amounts to a disagreement over policy considerations, not an indication of the arbitrariness, capriciousness, or unreasonableness of the regulation in question. Consequently, the Court finds that § 1.704(d) is

a valid interpretation of the PTA statute for this reason as well. The Court grants Defendant's Motion for Summary Judgment and denies Plaintiffs' Motion for Summary Judgment because Plaintiffs' have not demonstrated that § 1.704(d) is arbitrary, capricious, or otherwise not in accordance with law.

c. Plaintiffs' Argument That 37 C.F.R. § 1.704(d)(1) is Arbitrary, Capricious, or Otherwise Not In Accordance With Law Fails Because Plaintiffs Did Not Raise This Issue During Administrative Review

The Court grants Defendant's Motion for Summary Judgment and denies Plaintiffs' Motion for Summary Judgment because during administrative review, Plaintiffs' failed to raise the argument that 37 C.F.R. § 1.704(d)(1) is arbitrary, capricious, or otherwise not in accordance with law. Issues not raised before the federal agency during administrative proceedings, are waived and will not be considered by a court on review. *Wallaesa v. FAA*, 824 F.3d 1071, 1078 (D.C. Cir. 2016) (citing *Nuclear Energy Inst., Inc. v. EPA*, 373 F.3d 1251, 1297 (D.C. Cir. 2004)). "This rule applies with no less force to a statutory interpretation claim not brought to an agency's attention: [R]espect for agencies' proper role in the *Chevron* framework requires that the [C]ourt be particularly careful to ensure that challenges to an agency's interpretation of its governing statute are first raised in the administrative forum." *Nuclear Energy Inst.*, 373 F.3d at 1297 (internal quotation marks and citation omitted).

Here, the Administrative Record lacks any semblance of an argument by Plaintiffs that addresses the arbitrariness or capriciousness of § 1.704(d)(1), nor does the record reflect an argument that suggests § 1.704(d)(1) is otherwise not in accordance with the law. *See* Administrative Record at A429-450. Accordingly, for this separate reason, the Court grants

Defendant's Motion for Summary Judgment and Denies Plaintiff's Motion for Summary Judgment.

d. Plaintiffs' Fail To State A Taking Claim

Lastly, Plaintiffs' argument that the PTO's PTA deduction amounts to a governmental "taking" without just compensation, in violation of the Fifth Amendment, is unavailing. The Takings Clause of the Fifth Amendment "prohibits the government from taking private property for public use without just compensation." *Palazzolo v. Rhode Island*, 533 U.S. 606, 617 (2001). However, the Fifth Amendment's proscription against the taking of private property without just compensation does not "compensate the owner of the consequences of his own neglect in" preserving ownership rights. *Novartis AG v. Lee*, 740 F.3d 593, 600 (Fed. Cir. 2014) (quoting *United States v. Locke*, 471 U.S. 84, 107 (1985)). Here, because it was only Plaintiffs failure to comply with the 30 day grace period that prevented Plaintiffs from securing additional patent term adjustment, Plaintiffs' challenge as an uncompensated taking fails. Consequently, the Court grants Defendant's Motion for Summary Judgment and denies Plaintiffs' Motion for Summary Judgment.

CONCLUSION

The Court grants Defendant's Motion for Summary Judgment and denies Plaintiffs' Motion for Summary Judgment for three reasons. First, the Court holds that the Federal Circuit's decision in *Gilead Sciences, Inc. v. Lee*, 778 F.3d 1341 (Fed. Cir. 2015) forecloses Plaintiffs' claim that 37 C.F.R. § 1.704(c)(8) is arbitrary, capricious, or otherwise not in accordance with law. Second, the Court finds that 37 C.F.R. § 1.704(d)(1) is similarly not arbitrary, capricious, or otherwise not in accordance with law because Plaintiffs have not

demonstrated that § 1.704(d)(1) reflects an inappropriate interpretation of the PTA statute. Additionally, Plaintiffs failed to assert the argument that § 1.704(d)(1) is arbitrary, capricious, or otherwise not in accordance with law during administrative review. Third, Plaintiffs have failed to demonstrate that a government taking has occurred.

For the reasons stated above, it is hereby

ORDERED that Plaintiffs Supernus Pharmaceuticals and United Therapeutics Corporation Motion for Summary Judgment (Dkts. 15, 16) is **DENIED**.

IT IS FURTHER ORDERED Defendant PTO's Motion for Summary Judgment (Dkts. 18, 19) is **GRANTED**.

IT IS SO ORDERED.

ENTERED this 18th day of October, 2016.

Alexandria, Virginia
10/18/2016

/s/
Gerald Bruce Lee
United States District Judge